



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,952	01/03/2001	Rok Grahek	2260/106	8999

7590 04/22/2003
Timothy M Murphy
Bromberg & Sunstein
125 Summer Street
Boston, MA 02110

EXAMINER

SHAMEEM, GOLAM M

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,952

Applicant(s)

GRAHEK ET AL.

Examiner

Golam M M Shameem

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action supersedes the previous office action of paper No. 7 which has been entered in the file.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 drawn to a process for preparing a HMG-CoA reductase inhibitor by a chromatography technique, classified in class 210, with several subclasses.
- II. Claims 4-25 drawn to another process for preparing a HMG-CoA reductase inhibitor by a chromatography technique, classified in class 210, with several subclasses.
- III. Claims 26-27 drawn to another process for preparing a HMG-CoA reductase inhibitor by a chromatography technique, classified in class 210, with several subclasses.
- IV. Claims 28-43 drawn to a HMG-CoA reductase inhibitor, classified in class 549, with several subclasses.
- V. Claims 44-47 drawn to another process for preparing a HMG-CoA reductase inhibitor by a chromatography technique, classified in class 210, with several subclasses.

The above Invention groups represent general areas wherein the Inventions are independent and distinct, each from the other because of the following reasons:

Invention groups I-III, V and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

Art Unit: 1626

claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the process as claimed can be made at least one materially different process as demonstrated throughout the specification and Invention groups I-III and V, which are directed to several processes of preparing the product.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions are drawn to distinct processes of preparing compound of I-III and V requiring different search strategies because of the different reactive steps and conditions involved in each group.

Invention set I-III and V are distinct and independent from Invention IV because they are directed to different statutory classes of invention and, the practice of Invention I-III would not result in the practice of the other invention (group IV) and to search all the above groups in a single application would be an undue burden on the Examiner. Therefore a separate search considerations are involved, which would impose a burden if unrestricted. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purpose as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for

Art Unit: 1626

examination purposes as indicated is proper. Furthermore, the search required for any groups, such as group I is not required for other group, such as group IV.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is 703-305-0116. The Examiner can normally be reached on 8:30AM-5:00 PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for after final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1


Alan Rotman
Supervisory Patent Examiner
Art Unit 1625, Group 1620
Technology Center 1

April 18, 2003